

Third Party Governance of Industry-Sponsored Tobacco Product Research: A Public Workshop



***Food and Drug Administration (FDA)
Center for Tobacco Products
9200 Corporate Boulevard, Room 020B
Rockville, Maryland 20850
March 19-20, 2013***

Tuesday, March 19

- 8:30 a.m.** **Welcome and Overview**
- Workshop Overview and Format
 - Introduction of Workshop Moderator – Abby Dilley - RESOLVE, Inc.
- 9:00 a.m.** **Governance of Studies: Summary of IOM deliberations and recommendations**
Daniel Carpenter, PhD
Allie S. Freed Professor of Government
Department of Government
Harvard University
- 9:40 a.m.** **Challenges with Tobacco Industry-Sponsored Research**
- David Dobbins, JD** - American Legacy Foundation
Joanna Cohen, PhD - Institute for Global Tobacco Control, Johns Hopkins Bloomberg School of Public Health
- 10:30 a.m.** **Break**
- 10:45a.m.** **Matthew Myers, JD** - Campaign for Tobacco Free Kids
Mark Parascandola, PhD, MPH - Division of Cancer Control and Population Sciences,
National Cancer Institute, National Institutes of Health
Eric Donny, PhD - University of Pittsburgh
- 12:00 p.m.** **LUNCH (on your own)**
- 1:00 p.m.** **Q&A Session Led by Moderator**
- 2:00 p.m.** **Models from Other Arenas, Lessons Learned, and Potential Application to Tobacco**
- Richard Kuntz, MD, MSc** - Medtronic
- 3:00 p.m.** **Break**
- 3:15 p.m.** **Eric Peterson, MD, MPH** - Duke Clinical Research Institute
Mark Parascandola, PhD, MPH
- 4:00 p.m.** **Q&A Session Led by Moderator**
- 5:00 p.m.** **Adjourn**

Third Party Governance of Industry-Sponsored Tobacco
Product Research – Day 2

Wednesday, March 20

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| 8:30 a.m. | Introduction |
| 9:00a.m. | Public comment session (10 minutes each) |
| 9:30 a.m. | Challenges in Conducting Industry-Sponsored Research

Scott Ballin, JD
Donald Graff, PharmD - Celerion |
| 10:00 a.m. | Break |
| 10:45 a.m. | Lars-Erik Rutqvist, MD, PhD - Swedish Match
Michael Ogden, PhD - RAI Service Companies, R.J. Reynolds Tobacco Company
Justine Williamson, PhD - British American Tobacco
Jeffrey Walker, MD - Altria Client Services
Michael Hufford, PhD - e-Nicotine Technology |
| 11:45 a.m. | Q&A Session Led by Moderator |
| 12:45 p.m. | Concluding Comments |
| 1:00 p.m. | Adjourn |

The Food and Drug Administration, Center for Tobacco Products, Office of Science welcomes public comments on the topic of Third Party Governance of Industry-sponsored Tobacco Product Research. A docket for this topic will be opened soon. Please check the workshop webpage at <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm336166.htm> for instructions on submitting comments to the docket.

**The use of tobacco products is prohibited at all FDA facilities,
including buildings, grounds, and parking structures.**